DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

AUG 19 2009

Re: Emend for Injection
Docket No.: FDA-2009-E-0057

The Honorable Jon Dudas
Undersecretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Dudas:

This is in regard to the application for patent term extension for U.S. Patent No. 5,691,336, filed by Merck & Co., Inc., under 35 U.S.C. section 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Emend for Injection (fosaprepitant meglumine), the human drug product claimed by the patent.

The total length of the regulatory review period for Emend for Injection (fosaprepitant meglumine) is 4,473 days. Of this time, 3,810 days occurred during the testing phase and 663 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: October 29, 1995.

   The applicant claims October 28, 1995, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was October 29, 1995, which was 30 days after FDA receipt of the IND.

2. The date the application was initially submitted with respect to the human drug product under section 505 of the Federal Food, Drug, and Cosmetic Act: April 3, 2006.

   The applicant claims March 31, 2006, as the date the new drug application (NDA) for Emend for Injection (NDA 22-023) was initially submitted. However, FDA records indicate that NDA 22-023 was submitted on April 3, 2006.

3. The date the application was approved: January 25, 2008.

   FDA has verified the applicant's claim that NDA 22-023 was approved on January 25, 2008.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. section 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: J. Eric Thies
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